



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0001]

Pathogen Reduction Technologies for Blood Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Pathogen Reduction Technologies for Blood Safety.” The purpose of the public workshop is to foster the development and implementation of pathogen reduction technologies for blood components intended for transfusion. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government agencies.

DATES: The public workshop will be held on November 29, 2018, from 8 a.m. to 5 p.m., and on November 30, 2018, from 9 a.m. to 1 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-8010, email:

[CBERPublicEvents@fda.hhs.gov](mailto:CBERPublicEvents@fda.hhs.gov) (subject line: Pathogen Reduction Technology and Blood Safety).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Pathogen reduction technology has the potential to improve blood safety by reducing or eliminating infectious organisms, including bacteria, viruses, and parasites, from blood components intended for transfusion. FDA granted approvals for use of a pathogen reduction technology platform in manufacturing plasma and apheresis platelets for transfusion. Ideally, pathogen reduction technology should also be available for whole blood and red blood cells. Implementation of safe and effective pathogen reduction technology may also permit alternative donor screening or donation testing strategies in the future. The purpose of the public workshop is to foster the development and implementation of pathogen reduction technologies for all blood components intended for transfusion.

##### II. Topics for Discussion at the Public Workshop

The first day of the workshop will include presentations and panel discussions on the following topics: (1) transfusion-transmitted infectious agents and their impact on blood safety; (2) status of pathogen reduction technology for blood components intended for transfusion, including challenges to implementation in the United States; and (3) the development of pathogen reduction technology for whole blood and red blood cells.

The second day of the workshop will include presentations and panel discussions on the following topics: (1) emerging pathogen reduction technologies and alternative approaches to controlling risk; (2) potential funding opportunities for research; and (3) a summary of all workshop sessions, panel discussions, and future directions.

### III. Participating in the Public Workshop

*Registration:* To register for the public workshop, please visit the following website: <https://www.eventbrite.com/e/pathogen-reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by November 8, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided, beginning at 7 a.m.

If you need special accommodations, due to a disability, please contact Loni Warren Henderson or Sherri Revell no later than November 19, 2018 (see FOR FURTHER INFORMATION CONTACT). Request for sign language interpretation or Computer Aided Realtime Translation (CART)/captioning should be made 2 weeks in advance of the event, no later than November 15, 2018. A request for either interpreting or captioning should be sent directly to the FDA Interpreting Services Staff email account: [interpreting.services@oc.fda.gov](mailto:interpreting.services@oc.fda.gov).

*Streaming Webcast of the Public Workshop:* This public workshop will also be webcast. Individuals who wish to view the webcast should register for the workshop at

<https://www.eventbrite.com/e/pathogen-reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605>. A link to the live webcast will be provided upon registration.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at <https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

Dated: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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